

## Patent Claims

1. A process for preventing the demyelination of nerve fibers in the nervous system of a human being wherein said human being is treated with an amount of nerve growth factor (NGF) or active fragments of NGF effective to prevent demyelination. *Sum a1*
2. The process according to claim 1, wherein said fragments are selected from the group consisting of NGF 2.5S and NGF 7S. *62*
3. The process according to claim 1, wherein said nerve growth factor is human recombinant NGF- $\beta$ . *Sum a2*
4. The process according to claim 1, further comprising the administration of at least one protease inhibitor in combination with said NGF. *4*
5. The process according to claim 4, wherein said protease inhibitor is aprotinin. *3*
6. The method according to claim 1, wherein said NGF is administered to a patient in need of such treatment and said NGF is administered in an amount sufficient to produce a concentration of NGF or an active fragment of NGF between 0.05  $\mu$ g and 5  $\mu$ g/kg body weight. *Sum a3*
7. A pharmaceutical composition for the treatment of diseases in which demyelination of nerve fibers occurs, comprising NGF or an active fragment thereof in combination with a pharmaceutical vehicle, auxiliary substance, filler or diluent.
8. The composition according to claim 7, wherein said fragment is selected from the group consisting of NGF 2.5S and NGF 7S.
9. The composition according to claim 7, wherein said NGF is human recombinant NGF- $\beta$ .
10. The composition according to claim 7, further comprising at least one protease inhibitor in an amount sufficient to prevent inactivation of NGF by proteases.
11. The composition according to claim 10, wherein said protease inhibitor is aprotinin.

Sub 24 12. A process for preventing further demyelination in a patient having a disease in which a demyelination of nerve fibers occurs, comprising administering an amount of nerve growth factor or an active fragment thereof effective to prevent further demyelination.

7 13. The process according to claim 12, wherein the nerve growth factor is administered intravenously or intrathecally.

Sub 25 14. A method for preventing further demyelination in a patient having an inflammatory disease of the optic nerve, comprising administering an effective amount of NGF or an active fragment of NGF selected from the group consisting of NGF 2.5S and NGF 7S.

9 15. The method according to claim 14, wherein said effective amount of NGF or an active fragment of NGF is between 10-300 pg NGF/ml blood.

16. A kit for preventing further demyelination of nerve fibers, comprising NGF and at least one protease inhibitor in separate containers.

Sub 27 17. A method for preventing demyelination in a subject having an inflammatory disease of a nervous tissue, said method comprising administering an effective amount of NGF, an NGF analogue, or an active fragment of NGF wherein said effective amount is sufficient to downregulate the production of interferon  $\gamma$  by T cells infiltrating the central nervous system.

18. The method of claim 17, wherein said method comprises administering NGF or an active fragment of NGF.

11 19. The method of claim 17, wherein said effective amount is sufficient to upregulate the production of IL-10 in glial cells in the central nervous system.

- 12 ~~10~~. The method of claim ~~17~~<sup>10</sup>, wherein said inflammatory disease is autoimmune encephalomyelitis.
- 13 ~~11~~. The method of claim ~~17~~<sup>10</sup>, wherein said inflammatory disease is multiple sclerosis.
- 14 ~~22~~. The method of claim ~~17~~<sup>10</sup>, wherein said subject is a human.
- 15 ~~23~~. The method of claim ~~17~~<sup>10</sup>, wherein said subject is a non-human mammal.
24. The method of claim ~~17~~<sup>10</sup>, wherein said active fragment of NGF is selected from the group consisting of NGF ~~25S~~<sup>10</sup> and NGF 7S.
- 16 ~~25~~. The method of claim ~~17~~<sup>10</sup>, wherein said NGF is human recombinant NGF- $\beta$ .
26. A kit for preventing further demyelination of nerve fibers, said kit comprising NGF and instructional materials teaching the use of NGF to prevent further demyelination of nerve fibers.
27. The kit of claim 26, wherein said instructional materials teach the use of NGF to downregulate the production of interferon  $\gamma$  by T cells infiltrating the CNS.
28. The kit of claim ~~26~~<sup>10</sup>, wherein said instructional materials teach the use of NGF to upregulate the production of IL-10 by glial cells..